REMARKS

I. Status of the Application

Claims 1-23 were filed in the original application. In the Response to the Restriction Requirement mailed June 13, 2006, claims 1-12 were cancelled. In the present Amendment and Response to the Office Action mailed May 3, 2007, claims 15-19, 22, and 23 are cancelled, and claims 13, 14, 20 and 21 are amended. The Applicants note that all amendments and cancellations of claims are made without acquiescing to any of the Examiner's arguments or rejections, and solely for the purpose of expediting the patent application process in a manner consistent with the PTO's Patent Business Goals (PBG),[1] and without waiving the right to prosecute the amended or cancelled claims (or similar claims) in the future.

In the present Amendment and Response to the Office Action mailed May 3, 2007, claims 24-26 are newly added. Support for the newly added claims may be found throughout the Specification and Drawings. Support for claim 24 may be found, for example, at page 10, lines 1-4:

> "As used herein, the term "subject" refers to any animal (*e.g.*, a mammal), including, but not limited to, humans, non-human primates, rodents, and the like, which is to be the recipient of a particular treatment. Typically, the terms "subject" and "patient" are used interchangeably herein in reference to a human subject."

Support for claim 25 may be found, for example, at page 14, lines 12-17:

> "As used herein, the term "antibody" encompasses polyclonal and monoclonal antibody preparations including hybrid antibodies, altered antibodies, $F(ab')_2$ fragments, F(ab) fragments, F_v fragments, single domain antibodies, chimeric

1 65 Fed. Reg. 54603 (Sept. 8, 2000).

antibodies, humanized antibodies, and functional fragments thereof, which retain specificity for vimentin. Thus, if the antibody is to be used in a human, the antibody can be "humanized" in order to reduce immunogenicity yet retain activity.

Support for claim 26 may be found, for example, at page 64, lines 4-6.

"The formulations of this invention are useful for parenteral administration, such as intravenous, subcutaneous, intramuscular, and intraperitoneal."

Thus, claims 13, 14, 20, 21 and 24-26 are currently pending in the application.

In the Final Office Action of May 3, 2007 the Information Disclosure Statement is noted to be incomplete, there are 3 objections to the Specification, and there are 5 rejections. The currently pending notation, objections and rejections are:

1. The Information Disclosure Statement filed July 17, 2006 and considered by the Examiner is noted to be missing pages 3, 5, 6, and 7 of 8.
2. The Examiner notes that the first page of the disclosure is not numbered, and requests that "1" be added to the first page.
3. The Examiner notes that trademarks are present in the application, and requests that they be capitalized and accompanied by the generic terminology.
4. The Examiner notes that Table I. on page 84 of the disclosure recites sequences without including the appropriate sequence identification numbers and requests that the corresponding sequence identification numbers be added.
5. Claims 13-23 are rejected under 35 U.S.C. 112, second paragraph as allegedly being indefinite for failing to particularly point out and distinctly claim the subject matter which the Applicants regard as the invention.

6. Claims 13-15 are rejected under 35 U.S.C. 102(b) as allegedly being anticipated by Steinberg et al. (Journal of Molecular and Cellular Cardiology, Vol. 33, No. 6/01, page A104) (hereinafter "Steinberg").
7. Claims 16 and 20-21 are rejected under 35 U.S.C. 103(a) as allegedly being obvious over Steinberg in view of Yatsunami et al. (Biochemical and Biophysical Research Communications, 1991, Volr 177, NO. 3, pages 1165-1170) (hereinafter Yatsunami").
8. Claims 17 and 18 are rejected under 35 U.S.C. 103(a) as allegedly being obvious over Steinberg in view of Rasmussen et al. (Environmental Health Perspectives, Vol. 84, March 1990, pages 31-34) (hereinafter "Rasmussen").
9. Claims 19, 22 and 34 are rejected under 35 U.S.C. 103(a) as being obvious over Steinberg in view of Vorgias et al. (Bioscience Reports, 986, Fol. 6, No. 1, pages 57-64) (hereinafter "Vorgias")

II. The Information Disclosure Statement

In the Office Action mailed May 3, 2007 the Examiner notes that only pages 1, 2, 4 and 8 of the originally filed statement have been received. Accordingly, a second complete version of the originally filed Information Disclosure Statement is re-filed with the present Amendment and Response to the Office Action of May 3, 2007.

III. In the Specification

A. Disclosure Page Number 1

In the Office Action of May 3, 2007 the Examiner notes that the first page of the disclosure is not numbered. Accordingly, in the present Amendment and Response to the Office Action of May 3, 2007, the Specification is amended to include "1" in the footer of the first page.

B. Trademarks

In the Office Action of May 3, 2007 the Examiner notes that trademarks in the Specification should be capitalized wherever they appear, and be accompanied by generic terminology. Accordingly, in the present Amendment and Response to Office Action of May 3, 2007 paragraphs of the Specification with trademarks are amended.

C. Sequence Compliance

In the Office Action of May 3, 2007 the Examiner notes that:

> "Table I on page 84 of the disclosure recites sequences without including the appropriate sequence identification numbers." (Office Action of May 3, 2007, page 3.)

Accordingly, Table I is amended herein to include sequence identification numbers as described in the amendment to the Specification mailed November 21, 2006.

III. The Claims are Definite

1. Claim 13 is Definite

In the Office Action of May 3, 2007 the Examiner notes:

> "Claim 13 is directed to a method for pathogen killing. However, the method steps (a-b) merely recited the measurement of vimentin. The correlative step that links the method to its intended utility is missing. It is suggested that a correlation step is added to the method in order to obviate this rejection. Appropriate correction is required." (Office Action of May 3, 2007, page 4.)

The Applicants respectfully disagree with the Examiner's assertion. However, in order to further the business interests of the Applicants, and while reserving the right to prosecute that original (or similar) claims in the future, the Applicants have amended claim 13 to read "c) administering said anti-vimentin antibody to said subject under conditions such that said pathogen is killed."

In view of the above, the Applicants request that this rejection be withdrawn.

2. Claims 20 and 21 are Definite

In the Office Action of May 3, 2007 the Examiner notes:

"Claims 20 and 21 are vague and indefinite in reciting antibodies because it is not clear as to what the antibodies will bind." (Office Action of May 4, 2007.)

The Applicants respectfully disagree with the Examiner's assertion. However, in order to further the business interests of the Applicants, and while reserving the right to prosecute that original (or similar) claims in the future, in the present Amendment and Response to the Office Action of May 3, 2007, the Applicants have amended claim 20 to read "The method of claim 13, wherein said anti-vimentin antibody comprises a monoclonal antibody." As well, claim 21 has been amended to read "The method of claim 13, wherein said anti-vimentin antibody comprises a polyclonal antibody."

In view of the above, the Applicants request that this rejection be withdrawn.

3. Claim 16

In the Office Action of May 3, 2007 the Examiner notes;

"Claim 16 is vague and indefinite because it is not clear how the amount of bioavailable vimentin will be decreased in claim 13 and but (sic) simultaneously increased in claim 16." (Office Action of May 3, 2007, page 4.)

In the present Amendment and Response to the Office Action of May 3, 2007 claim 16 is cancelled, thereby rendering the Examiner's rejection moot.

IV. Steinberg Does Not Anticipate the Claims

In the Office Action of May 3, 2007 the Examiner notes:

"Steinberg et al disclose procedures employing Go6983 (PKC inhibitor) to augment cardiomyocyte apoptosis in *Pasteurella multocida* toxin (rPMT) treated cells. . . . With respect to the pathogen being killed, it is noted that Go6983 augmented the effects of the toxin." (Office Action of May 3, 2007, page 5.)

The Applicants respectfully disagree with the Examiner's rejection. The Federal Circuit has stated the relevant analysis for anticipation as follows:

"A claim is anticipated only if each and every element as set forth in the claims is found, either expressly or inherently described, in a single prior art reference."[2]

The Applicants respectfully submit that the reference cited by the Examiner fails to teach each and every element as set forth in the claims. For example, Steinberg does not teach or suggest an anti-vimentin antibody. Steinberg does not teach or suggest pathogen killing with an anti-vimentin antibody. Steinberg does not teach or suggest pathogen killing by administration of an anti-vimentin antibody to a subject.

Clearly, Steinberg fails to teach or suggest not one, but multiple elements of the presently claimed invention. In view of the above, the Applicants request that this rejection be withdrawn.

V. The Claims are not Obvious Over Steinberg in view of Yatsunami

In the Office Action of May 3, 2007 the Examiner notes:

"It would have been prima facie obvious to one of ordinary skill at the time the invention was made to evaluate okadaic acid and detect vimentin with antibodies as exemplified by Yatsumani et al. in the method of Steinberg et al. because Yatsumani et al taught that the effects of okadaic acid class of tumor promoters, which are reflected in the hyperphosphorylation of vimentin in primary human

[2] *Verdegaal Bros. V. Union Oil of California*, 2 USPQ2d 1051, 1053 (Fed.Cir. 1987).

fibroblasts, should be studied in relation to cell cycle regulation." (Office Action of May 3, 2007, page 7.)

The Applicants respectfully disagree with the Examiner's rejection. First, claim 16 is cancelled herein, thereby rendering the Examiner's rejection of claim 17 moot.

Second, with regard to claims 20 and 21, a *prima facie* case of obviousness requires the Examiner to cite to a reference which a) discloses all the elements of the claimed invention, b) suggests or motivates one of ordinary skill in the art to combine the claim elements to yield the claimed invention, and c) provides a reasonable expectation of success should the claimed combination be carried out. Failure to establish any one of these three requirements negates a finding of a *prima facie* case and, without more, entitles the Applicants to allowance of the claims in issue. (MPEP)

The Applicants submit that Steinberg in view of Yatsunami fails to teach or suggest pathogen killing by administering an anti-vimentin antibody to a subject. Nor does Steinberg in view of Yatsunami teach or suggest pathogen killing in a subject. Moreover, Steinberg in view of Yatsunami does not teach or suggest pathogen killing.

Clearly, the Examiner's combination of Steinberg in view of Yatsunami is missing not just one but multiple elements of the claims set forth in the present application.

In view of the above, the Applicants request that this rejection be withdrawn.

VI. Claims 17 and 18

In the Office Action of May 3, 2007 the Examiner notes:

"It would have been prima facie obvious to one of ordinary skill at the time the invention was made to evaluate/modify vimentin secretion with CaM expression vectors that produced CaM antisense RNA as taught by Rasmussen et al. in the method of Steinberg et al. . . ." (Office Action of May 3, 2007, page 8.)

In the present Amendment and Response to Office Action of May 3, 2007 claims 17 and 18 are cancelled, thereby rendering the Examiner's rejection moot.

VII. Claims 19, 22 and 23

In the Office Action of May 3, 2007 the Examiner notes:

> "It would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to utilize a neutral thiol proteinase compounds as vimentin inhibitors as expemplified by Vorgias et al. in the method of Stieinberg et al. . . ." (Office Action of May 3, 2007, apge 9.)

In the present Amendment and Response to Office Action of May 3, 2007 claims 19, 22 and 23 are cancelled, thereby rendering the Examiner's rejection moot.

CONCLUSION

All grounds of rejection of the Office Action dated May 3, 2007, have been addressed, and reconsideration of the application is respectfully requested. It is respectfully submitted that the Applicant's claims should be passed into allowance. Should the Examiner believe that a telephone interview would aid in the prosecution of this application, Applicants encourage the Examiner to call the undersigned collect at (608) 218-6900.

Dated: October 5, 2007

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